

## **REMARKS**

### ***Status of the Claims***

Claims 1-19, 21-24, 27-33, 35-40, and 65-76 are presently pending in this application. Claims 5, 11, and 27-33 have been withdrawn. Reconsideration is respectfully requested in view of the amendments and remarks herein.

### ***Amendments to the Claims***

Claims 1 and 35 are amended to recite that the first and second pathways have at least a proximal portion at least partially in communication with one another. Claim 35 is also amended to correct antecedent basis. Claim 66 is cancelled, and claim 65 is amended to include the subject matter of claim 66. Support for these amendments can be found throughout the specification and drawings. No new matter is added.

### ***Status of Previously Submitted Information Disclosure Statements***

All of the art cited in the Information Disclosure Statement submitted by the Applicant on October 12, 2007 has not been noted as considered by the Examiner. Applicant again respectfully requests the Examiner to initial Cite No. AD, U.S. Published Application 20040019353-A1.

### ***Rejections Pursuant to 35 U.S.C. § 102***

Claim 75 is rejected pursuant to 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,306,278 of Dahl et al. ("Dahl"). Applicant respectfully disagrees.

Independent claim 75 recites, in relevant part, a housing having first and second pathways at least partially in communication with one another, where at least a portion of each pathway is defined by a substantially elongate, semi-cylindrical sidewall of the housing. Applicant cannot locate any substantially elongate, semi-cylindrical sidewalls in Dahl, much less any substantially elongate, semi-cylindrical sidewalls that define at least a portion of the passages (26, 28), which the Examiner likens to the first and second pathways. The passages (26, 28) are merely tunnels formed within a guide head (12), which the Examiner likens to a guide member. Neither of the passages (26, 28) are defined by a semi-cylindrical sidewall. Rather, each passage is defined by a purely cylindrical sidewall.

Accordingly, independent claim 75 distinguishes over Dahl and represents allowable subject matter.

***Rejections Pursuant to 35 U.S.C. § 103***

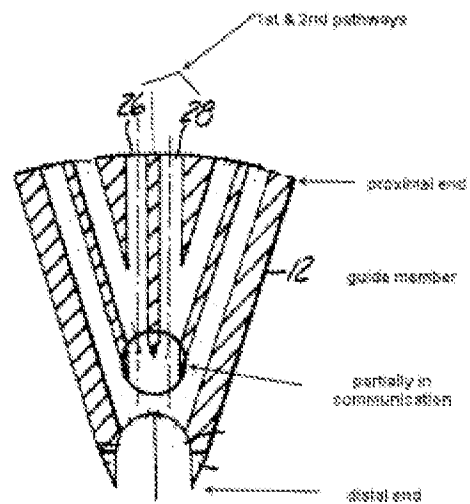
***Claims 1-4, 6-10, 12-19, 35-40, and 65-69***

Claims 1-4, 6-10, 12-19, 35-40, and 65-69 are rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Dahl in view of U.S. Design Patent No. 433,506 of Asfora (“Asfora”). Applicant respectfully disagrees.

***Independent Claim 1***

Independent claim 1 recites, in relevant part, a guide member coupled to the distal end of an elongate shaft and including first and second pathways having at least a proximal portion at least partially in communication with one another and extending therethrough in a fixed relation to one another. Claim 1 further recites at least one alignment element adapted to interact with a spinal fixation element to position the guide member with respect to the spinal fixation element such that the first and second pathways in the guide member are aligned with a pair of corresponding thru bores formed in the spinal fixation element.

Dahl does not disclose a guide member coupled to the distal end of the elongate shaft and including first and second pathways having at least a proximal portion at least partially in communication with one another and extending therethrough in a fixed relation to one another. As clearly seen in the Examiner’s annotated version of Dahl’s Figure 3 at right, the passages (26, 28) do not have a proximal portion at least partially in communication with each other. Indeed, the proximal portions of the passages (26, 28) are entirely separate.



Dahl also does not disclose first and second pathways in the guide member that can be aligned with a pair of corresponding thru bores formed in the spinal fixation element. As clearly seen in the

annotated version of Figure 3 above, the passages (26, 28) converge at the distal end (34) of the guide head (12), thereby forming a single distal opening. A single opening cannot be aligned with a *pair of corresponding* thru bores.

Asfora is relied on for another feature of claim 1, namely that the elongated shaft has a proximal end being positioned at an angle other than 0 degrees with respect to the distal end of the shaft, and does not remedy the deficiencies of Dahl.

Further, it would not have been obvious to combine Dahl with Asfora because such a modification would not “facilitate the drilling process during the implantation of a specific device” as suggested by the Examiner on page 5 of the Office Action. Indeed, a person skilled in the art would have no reason or motivation to combine Dahl and Asfora. The strongest rationale for combining references is a recognition that some advantage or expected beneficial result would be produced by the combination. *See* MPEP § 2144. The device of Dahl already assures access to the passages (22, 24, 26, 28, 30, 32) at the proximal end (36) of the guide head (14) because the guide head’s axis (14) is offset at an angle from the axis (16) of the shaft (20) and handle (18). There is simply no need to position a proximal end of the shaft (20) at an angle from its distal end as disclosed in Asfora because the rotated axis (14) of the guide head (12) already helps ensure passage access without interference from the shaft (20) and/or the handle (18).

Accordingly, independent claim 1, as well as claims 2-4, 9, 10, 17-19 which depend therefrom, distinguish over Dahl and Asfora, taken alone or in combination, and represent allowable subject matter.

**Independent Claim 35**

Independent claim 35 recites, in relevant part, a guide device including opposed first and second pathways formed therein and having at least a proximal portion at least partially in communication with one another. Thus, claim 35, as well as claims 36-40 which depend therefrom, distinguish over Dahl and Asfora for at least the reasons discussed herein for claim 1.

**Independent Claim 65**

Independent claim 65 recites, in relevant part, a guide member in the form of a substantially hollow housing having first and second pathways extending therethrough between proximal and distal

ends thereof, with the *first and second pathways including opposed, substantially semi-cylindrical pathways* formed within the hollow housing and being at least partially in communication with one another. As can be clearly seen in the annotated version of Figure 3 above, the passages (26, 28) are cylindrical tunnels formed within the guide head (12). The passages (26, 28) are not opposed, nor are they substantially semi-cylindrical. Asfora is relied on for another claim feature and does not remedy the deficiency of Dahl. Further, as discussed above, it would not have been obvious to combine Dahl with Asfora because the guide head's angled axis (14) ensures passage access.

Accordingly, independent claim 65, as well as claims 66-69 which depend therefrom, distinguish over Dahl and Asfora, taken alone or in combination, and represent allowable subject matter.

Claims 21-24 and 70-73

**Dahl in view of Asfora and further in view of Shapiro**

Claims 21-24 and 70-72 are rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Dahl in view of Asfora and further in view of U.S. Patent No. 5,324,295 of Shapiro ("Shapiro"). At least for the reasons explained above, independent claims 1 and 65 distinguish over Dahl in view of Asfora. Shapiro is relied on only for dependent claim features, namely a cut-out portion extending between the inferior and superior sidewalls, and does not remedy the deficiencies of Dahl and Asfora. Further, as explained further below, Shapiro does not teach or suggest a cut-out portion that terminates distal to the proximal end of the guide member and thus would not remedy the deficiencies of Dahl and Asfora even if the references could be combined as suggested by the Examiner. Accordingly, claims 21-24 and 70-72 are allowable at least because they depend from an allowable base claim.

**Dahl in view of Asfora and further in view of Serbousek**

Claims 21-24 and 70-72 are also rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Dahl in view of Asfora and further in view of U.S. Patent No. 6,066,142 of Serbousek et al. ("Serbousek"). The Examiner relies on Dahl and Asfora to teach the claimed invention but admits that neither Dahl nor Asfora discloses a C-shaped lateral sidewall for guiding implants, tools, and devices. The Examiner thus relies on Serbousek for this feature, arguing on page 7 of the Office Action that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to

modify the Dahl et al reference with the Asfora reference in order to direct and/or facilitate the guide of tools along the length of the guide as disclosed by the Serbousek et al reference.”

This rejection appears to be in error because none of claims 21-24 and 70-72 recite a C-shaped lateral sidewall. As discussed above, Dahl and Asfora do not make unpatentable independent claims 1 and 65, so claims 21-24 and 70-72 are allowable at least because they depend from an allowable base claim.

Applicant presumes that the Examiner intended to reject claim 73 over Dahl in view of Asfora and further in view of Serbousek because claim 73 is the only claim that recites a C-shaped lateral sidewall. Moreover, while claim 73 is listed as rejected in the Summary, claim 73 is not addressed in any rejection presented in the Office Action. If Applicant is misinterpreting the rejection, clarification is respectfully requested. If the Examiner rejects claim 73 on grounds other than Dahl in view of Asfora and further in view of Serbousek in an Office Action responding to this paper, Applicant respectfully requests that the Office Action be Non-Final as raising a new ground of rejection and to first establish a clear issue between the Examiner and Applicant. *See* MPEP § 706.07.

Independent claim 73 recites, in relevant part, an elongate shaft having proximal and distal ends, with the proximal end of the shaft being positioned at an angle other than 0 with respect to the distal end of the shaft. Claim 73 further recites a guide member including a first substantially C-shaped lateral sidewall for guiding implants, tools, and devices through the first thru bore in the spinal fixation element, and a second, opposed substantially C-shaped lateral sidewall for guiding implants, tools, and devices through the second thru bore in the spinal fixation element.

Addressing the Examiner’s presumed intended rejection, independent claim 73 is not unpatentable over Dahl in view of Asfora and further in view of Serbousek. The Examiner relies on Dahl to teach the claimed invention but admits that Dahl does not disclose the proximal end of the shaft being positioned at an angle other than 0 with respect to the distal end of the shaft and thus relies on Asfora for this feature. As discussed above, a person skilled in the art would not have combined Dahl and Asfora, and for at least this reason, claim 73 distinguishes over Dahl, Asfora, and Serbousek.

The Examiner further admits that Dahl as modified by Asfora does not disclose a C-shaped lateral sidewall for guiding implants, tools, and devices and thus relies on Serbousek for this feature. A

prima facie case of obviousness cannot be established by merely pointing out the existence of particular claim elements in the prior art. MPEP § 2143 and the Supreme Court's recent decision in *KSR Int'l Corp. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) underscores the deficiencies in the Office Action and the error of its obviousness rejection. The Supreme Court said that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR*, 127 S. Ct. at 1741. The Examiner states that it would be obvious for one having ordinary skill in the art to combine elements of Dahl, Asfora, and Serbousek but does not provide any analysis why that is true.

No person of ordinary skill in the art would combine Dahl, Asfora, and Serbousek. As mentioned above, the strongest rationale for combining references is a recognition that some advantage or expected beneficial result would be produced by the combination. *See* MPEP § 2144. There is no advantage to modifying the drill guide of Dahl to include a first substantially C-shaped lateral sidewall for guiding implants, tools, and devices through a first thru bore in a spinal fixation element, and a second, opposed substantially C-shaped lateral sidewall for guiding implants, tools, and devices through a second thru bore in the spinal fixation element. As clearly shown for example in Applicant's FIGS. 5B and 5D, first and second pathways (520, 522) are each defined by a substantially C-shaped sidewall and have a cut-out portion (528) formed therebetween. The cut-out portion (128) provides means of access or communication between the first and second pathways (520, 522) at least in part because the first and second pathways (520, 522) have substantially C-shaped sidewalls which do not fully enclose the pathways (520, 522), e.g., as cylindrical tunnels. Such means of access or communication between the first and second pathways (520, 522) can be advantageous, for example, by "provid[ing] the surgeon with improved visual access to a spinal fixation element positioned in relation to the guide member 518, as well as to tools and devices used in connection with the guide device 510." (Paragraph [0048].) In contrast, there would be absolutely no visual or other advantage to making the sidewalls of any of Dahl's passages (22, 24, 26, 28, 30, 32) substantially C-shaped. If any two of the passages (22, 24, 26, 28, 30, 32) of Dahl were altered to include the drill passages (224, 228) of Serbousek as suggested by the Examiner, the two passages and any tools disposed therein would be out of sight as contained within the solid guide head (12), the same as in Dahl's current, unaltered configuration. Functionality of Dahl's device could even decrease or be eliminated because any tool disposed through a passage altered to have a substantially C-shaped lateral sidewall within the guide head (12) would lose its direction at the distal end (34) where such a substantially C-shaped lateral sidewall would no longer exist.

Accordingly, independent claim 73 distinguishes over Dahl, Asfora, and Serbousek, taken alone or in combination, and represents allowable subject matter.

Claims 74 and 76

Claims 74 and 76 are rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Dahl in view of Asfora. Applicant respectfully disagrees.

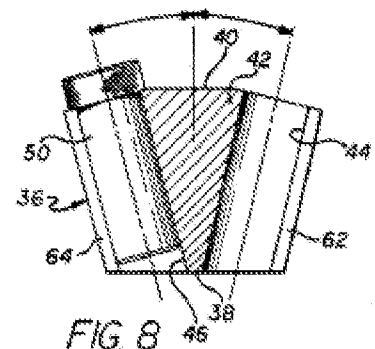
At the outset, Applicant notes that while the preamble rejecting claims 74 and 76 states the combination of Dahl and Asfora, the subsequent explanatory text apparently uses the combination of Dahl and Shapiro in rejecting claims 74 and 76. Applicant thus assumes that the Examiner intended to reject claims 74 and 76 over Dahl in view of Shapiro. Clarification is respectfully requested if the Examiner otherwise intended.

The Examiner relies on Dahl to teach the claimed invention but admits that Dahl does not disclose a cut-out portion extending between the inferior and superior sidewalls. The Examiner thus relies on Shapiro for this feature, arguing on page 7 of the Office Action that “[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Dahl et al reference with the Shapiro reference in order to direct and/or facilitate the guide of tools along the length of the guide.” However, even if Dahl could be combined with Shapiro, Shapiro does not remedy the deficiencies of Dahl as discussed below.

Claim 74

In relevant part, independent claim 74 recites a guide device including a guide member having opposed cut-out portions formed in superior and inferior sidewalls of the guide member, with the cut-out portion in the inferior sidewall extending from a distal end of the guide member and terminating distal to a proximal end of the guide member.

As shown in Figure 8, reproduced at right, Shapiro discloses a convergence guide (36) defining a pair of bores (44, 46) extending from the guide's distal side (40) to the guide's proximal side (38). *See* Col. 4, lines 55-59. The guide (36) also defines a pair of slots (62, 64) coextensive with the bores (44, 46). *See* Col. 5, lines 43-47. The slots



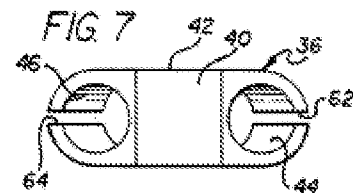
(62, 64) both clearly extend between the distal side (40) and the proximal side (38). Neither slot terminates distal to the proximal side (38) of the guide (36). The slots (62, 64) both extend between the distal side (40) and the proximal side (38) to allow passage of pins (24, 52). *See* Col. 5, lines 49-56. Therefore, even if the slots (62, 64) of Shapiro are considered to be cut-out portions formed in superior and inferior sidewalls of the guide (36) and were combined with Dahl as suggested by the Examiner, the combination would not teach the claimed invention.

### **Claim 76**

Independent claim 76 recites, in relevant part, a guide device including a guide member being in the form of a substantially hollow housing, and including opposed first and second cut-out portions extending in a proximal-distal direction and formed substantially between first and second pathways of the guide member. The second cut-out portion extends from a distal end of the housing and terminates distal to a proximal end of the housing.

As discussed above regarding claim 74, Shapiro does not disclose a cut-out portion that terminates distal to a proximal end of a guide member.

Additionally, Shapiro does not disclose opposed first and second cut-out portions formed substantially between first and second pathways of the guide member. As shown in Figure 8 above and in Figure 7, reproduced at right, the opposite is true. The slots (62, 64) are clearly on opposite far sides of the bores (44, 46) and are not at all substantially between the bores (44, 46).



Accordingly, independent claims 74 and 76 distinguish over Dahl and Shapiro, taken alone or in combination, and represent allowable subject matter.

### **Conclusion**

Applicant submits that all claims are in condition for allowance for at least the reasons discussed above, and allowance thereof is respectfully requested. Applicant's amendment of the claims does not constitute a concession that the claims are not allowable in their unamended form. The Examiner is



encouraged to telephone the undersigned attorney for Applicant if such communication is deemed to expedite prosecution of this application.

Dated: August 5, 2008

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